IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION AT MEMPHIS

KEVIN CARTER, Individually, and on behalf of the minor children of CASEY S. CARTER, Deceased — PLAINTIFF

v. — No. 2:14-cv-01023-JTF-tmp

MEMPHIS OBSTETRICS & GYNECOLOGICAL ASSOCIATION, P.C. and LEA BANNISTER, M.D. — DEFENDANTS

Jury Trial Demanded

FIRST AMENDED COMPLAINT

COMES NOW the Plaintiff Kevin Carter, by and through his attorneys, Merkel & Cocke, P.A., and for his First Amended Complaint would show unto the Court as follows:

Parties

1. The Plaintiff Kevin Carter is an adult resident citizen of Olive Branch, Mississippi. Kevin Carter is the surviving spouse of Casey S. Carter, deceased. This Plaintiff brings this action as surviving spouse of Casey Carter pursuant to Tenn. Code Ann. §20-5-110, both individually and on behalf of the minor children of Casey S. Carter.

2. The Defendant Memphis Obstetrics & Gynecological Association, P.C. (hereafter "MOGA") is a Tennessee professional corporation with its principal place of business being located at 3775 Covington Pike, Memphis, TN. This Defendant may be served with process at by service upon its registered agent, George Wortham III, M.D., 3775 Covington Pike, Memphis, TN 38135.

3. The Defendant Lea Bannister, M.D. is a physician practicing in Memphis, Tennessee with MOGA. This Defendant may be served at her place of business.

Jurisdiction

4. This Court has jurisdiction over the parties and subject matter pursuant to 28 U.S.C. §1332 in that there is a complete diversity of citizenship between all plaintiffs and all defendants and the amount in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

Venue

5. Venue is proper in the United States District Court for the Western District of Tennessee, Western Division, in that the acts or omissions complained of occurred in whole or in part in Shelby County, Tennessee, a county within the Western Division.

Factual Statement

6. Casey Carter, deceased, was a 42 year mother of two minor children. Casey was married to Kevin Carter, who she began dating in high school.

7. Casey Carter was an executive working in the IT department of Federal Express.

8. On September 4, 2013, Casey Carter underwent a uterine ablation performed by Lea Bannister, M.D., a physician employee of MOGA. The ablation was performed at the MOGA's East offices located at 6215 Humphreys Blvd., Memphis, TN.

9. A uterine ablation is a medical procedure performed by gynecologists with the intent of destroying the endometrial lining of the uterus. The purpose of a uterine ablation is to stop excessive menstrual bleeding in women. Because it destroys the uterine lining it may only be done in women who no longer wish to have children.

10. Uterine ablations can be performed in a number of different ways, and a number of different ablation devices have been approved by the United States Food & Drug Administration ("FDA") for this purpose.

11. In general, ablation techniques involve using an approved device which is placed

through the cervix and into the uterus, with the application of a subsequent heat cycle to destroy the edometrial lining of the uterus.

12. The ablation procedure performed on Casey Carter by Dr. Bannister was performed using a "NovaSure" ablation device manufactured by Hologic, Inc. The NovaSure device is a Type III medical device subject to FDA approval for safety and efficacy. The NovaSure device comes with FDA approved warnings and instructions.

13. The NovaSure system involves the insertion of a disposable slender wand through the cervix. The physician then extends a triangular mesh to a preset width and depth to fill the uterus, and delivers a radiofrequency energy for approximately a 90 second cycle to destroy the endometrial lining.

14. The NovaSure control unit is designed in such a way that it calculates the power output based on the uterine cavity length and width measurements inputted by the operator. The controller measures the tissue electrical impedance and automatically controls the depth of the endo-myometrial ablation. The mesh is then retracted back into the wand and removed from the cervix.

15. Dr. Bannister performed the procedure in MOGA's East office. No contemporaneous note or report was prepared by Dr. Bannister with regard to the procedure.

16. Casey Carter died of septic shock two days after the ablation on September 6, 2013, at Methodist Hospital-Germantown while she was on the operating table undergoing surgery for a perforated bowel. Surgical and autopsy findings included three 3mm (millimeter) perforations of the anterior fundus of the uterus (front top), and a single 1 cm (centimeter) perforation of the small bowel.

17. On September 17, 2013, eleven days after Casey Carter died, and fourteen days after the ablation procedure, Dr. Bannister added a "procedure note" to the electronic medical record

of MOGA.

18. Plaintiff alleges that it is likely that Dr. Bannister prepared the report only after having met with her attorneys and after having consulted others, and, of course, knowing that Casey Carter had died of sepsis following uterus and bowel perforations. Because of these circumstances, the accuracy and completeness of the report is subject to substantial question.

19. As documented the report states:

Category: Chart Note

Priority: Routine **Provider:** Bannister, Lea

Chart Note: Proceedure: Hysteroscopy, D&C, Novasure Ablation
Date of Proceedure: 9/4/13
Anes: CRNA IV sedation
Assistant: Tish Olinger, R.N.
EBL< 10cc
Complications: None observed during proceedure
After IV sedation, speculum was used to visualize the cervix and cervical, vaginal area was prepped with betadine. Lidocaine was injected into the cervix at 12, 4, and 8:00 then anterior lip of cervix was grasped with a tenaculum. Uterine sounding was performed to determine the uterine length and the internal cervical os was dilated so as to allow passage of the hysteroscope with attached camera. The full endometrial cavity was inspected, both tubal ostia were noted and no abnormalities seen. The sharp currette was then used to obtain endometrial tissue which was sent to pathology.

Messages: Lea Bannister, MD 9/17/2013 1:57:37 PM
Continuation of Proceedure note entry 9-17-13
Internal cervical os was then dilated so as to allow passage of the Novasure catherter. Prior to insertion of catheter the instrument was deployed and retracted. The uterine length was set at 6.5 cm and catheter was placed at uterine fundus then retracted slightly followed by deployment of the instrument's arms. Maneuvers were then performed to asses uterine width which was determined to be 4.8cm. Pressure testing cycle was then initiated and completed on first attempt followed by initiation of the heating cycle. The heat cycle lasted for approximately 40 sec, shorter than expected; therefore, I retracted catheter's arms and removed the Novasure catheter. I then re-performed hysteroscopy and visualized good blanching and cautery effect of all surfaces with the exception of an approximate 4x3 cm pink endometrial surface at the mid uterine fundus. Decision was made to repeat ablation by re-insertion of the Novasure catheter with uterine length at 6.5cm and after proper deployment of instrument's arms, maneuvers were performed to determine uterine width of 4.5cm. Then pressure testing cycle was initiated but unsuccessful. The acorn cap was pused more fimly against the cervix and pressure testing cycle was then successful, followed by initiation and completion of a 30sec treatment cycle. All instruments were removed and no bleeding noted from operative sites. Patient tolerated proceedure well with no apparent complications. I spoke to Mrs. Carter approximately 10 minutes after proceedure and she was sitting up and in no apparent distress.
(Note this entry is being made to EMR after date of performance of proceedure on 9-4-13. I realized I had not prepared proceedure note after patient's death on 9-6-13.)

Entered By: Lea Bannister, MD	9/17/2013 1:57:37 PM
Closed By: Lea Bannister, MD	9/17/2013 1:57:37 PM
Electronically Approved by: Lea Bannister, MD	9/17/2013 1:57:00 PM

20. The application of two heats cycles as described by Dr. Bannister was in complete conflict with the FDA approved manufacturer's instructions and warnings.

21. Hologic, Inc., the manufacturer of the Novasure device, specifically provides in the "Instructions for Use and Controller Operator's Manual" which come with each disposable

device:

> **CAUTION**: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN TRAINED IN THE USE OF THE DEVICE.
>
> **Read all instructions, cautions and warnings prior to use. Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury.**
>
> ...
>
> **Physician Checklist**
>
> The physician must:
>
> - review and be familiar with the instructions and complete either a NovaSure training or be trained by a qualified physician.
>
> ...
>
> Adjunct personnel must be familiar with these instructions and other training materials prior to using the NovaSure system.
>
> **WARNINGS**
>
> **FAILURE TO FOLLOW ANY INSTRUCTIONS OR FAILURE TO HEED ANY WARNINGS COULD RESULT IN SERIOUS PATIENT INJURY.**
>
> **...**
>
> **THE NOVASURE PROCEDURE IS INTENDED TO BE PERFORMED ONLY ONCE DURING A SINGLE OPERATIVE VISIT. THERMAL INJURY TO THE BOWEL MAY OCCUR WHEN MULTIPLE NOVASURE THERAPY CYCLES ARE PERFORMED DURING THE SAME OPERATIVE VISIT.**
>
> **PRECAUTIONS**:
>
> The safety and effectiveness of the NovaSure system has not been fully evaluated in patients:
>
> ...
>
> - who have undergone a previous endometrial ablation including the NovaSure endometrial ablation procedure.

22. Dr. Bannister was reckless and grossly negligent in performing the ablation procedure twice in direct contrast to the manufacturer's warnings.

23. Although not described in any medical record prepared by Dr. Bannister, one or more individuals affiliated with MOGA subsequently reported to a representative of Hologic that

Casey Carter suffered a "bowel burn". See MAUDE[1] report 1222780-2013-00181. Hologic reported to the FDA that a "physician" affiliated with the "user facility" had reported:

> On (b)(6)[2] 2013, it was reported that a physician performed an uneventful NovaSure endoemetrial ablation on (b)(6) 2013. A post-ablation hysteroscopy was performed and "did not note any problems". The pt was discharged home. On (b)(6) 2013, the pt contacted the physician complaining of "abdominal and gas pains". The physician "instructed her how to deal with the pain (type of intervention is unk)". The pt was not seen by the physician. On (b)(6) 2013, the pt presented to the emergency room (er) and was "septic and had white blood cell count of 1.4". The pt expired in the operating room (or). On (b)(6) 2013 it was reported that the patient had "3 uterine perforations and **a bowel burn**" and "the time of expiration was 5:43 p.m. on (b)(6) 2013". We [Hologic, Inc.] have been unable to obtain add'l info surrounding this event. (emphasis added).

24. Plaintiff alleges Casey Carter's bowel was burned, resulting in a perforation, as a result of Dr. Bannister's misuse of the NovaSure device with two heat cycles in contravention of the manufacturer's warnings.

25. Had there been no injury to the bowel Casey Carter would not have developed peritonitis and would not have died of septic shock.

26. Dr. Bannister's "Procedure Note" indicates "Complications: None observed during the procedure" and "Patient tolerated procedure well with no apparent complications" and "I spoke with Mrs. Carter approximately 10 minutes after the procedure and she was sitting up in no apparent distress". Plaintiff alleges these reported facts are factually inaccurate.

27. Defendant MOGA has produced with its Rule 26 initial disclosures a handwritten note prepared by Tish Hickman, RN on September 7, 2013. That note indicates:

"[patient] c/o cramping and nausea upon awakening."

28. These symptoms are materially omitted in Dr. Bannister's after-the-fact "Procedure Note".

29. Dr. Bannister was negligent in failing to investigate the cramping and nausea, and to

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[1]MAUDE is an acronym for the FDA's Manufacturer and User Facility Device Experience data base. MAUDE data represents reports of adverse events involving regulated medical devices reported by manufacturers, user facilities and voluntary reporters. It has an online search feature, with patient name and other identifying information redacted.

[2] The symbol "(b)(6)" indicates a redaction by the FDA of identifying information.

recognize the three 3 mm perforations of the uterus at the time of the procedure.

30. Had perforations of the uterus been recognized at the time of the ablation procedure the suspicion of damage to adjacent organs, including the bowel, should have been very high. The acceptable standard of professional practice for gynecologists would have required appropriate tests and consults to rule out injury to other structures.

31. To a reasonable medical certainty, had additional procedures and studies been done the perforation of the small bowel would have been discovered.

32. Had the perforation to the small bowel been recognized the acceptable standard of professional practice would have required exploratory surgery and surgical repair as quickly as possible, irrigation of the abdomen, coverage with appropriate antibiotics, and close followup monitoring.

33. Had the perforation of the bowel been recognized on the day of the ablation, and the practices set forth in paragraph 21 been followed, to a reasonable medical probability Casey Carter would have survived.

34. No perforations of the uterus or bowel were recognized by Dr. Bannister, and instead Casey Carter was sent home with her husband.

35. An electronic chart note prepared by Tish Hickman, RN on September 6, 2013 (after Casey Carter had died) indicates that "written post-op instructions were discussed with and given to the pt who was taken by wheelchair to husband waiting in car." No such instructions are a part of the MOGA medical record.

36. On September 5, 2013 Casey Carter phoned the offices of MOGA with complaints of pain. The information was taken down by Barbie Archibald, on belief a receptionist for MOGA. The telephone message reads:

"Pt is post op - NovaSure c/o pain & nausea & unable to eat. c/o gas."

37. The telephone message was given to Tish Hickman, RN, a nurse employee of MOGA, who returned the call. Nurse Hickman documented the following:

TC [telephone call] Spoke with pt who c/o gas pain, constipation, and nausea 1 day post

> ablation. Advised to cont Phenergran 25 mg po [by mouth], discontinue Lortab which may be causing constipation/gas pain, may use Dulcolax Supp [suppository] for gas, avoid gas forming drinks and foods, and call back if sx persist.

Nurse Hickman phoned in a prescription for Dulcolax.

38. Upon belief, Nurse Hickman was present during the ablation, was aware of the second "burn", and aware of the complaints of cramping and nausea upon awakening. Nurse Hickman knew, or should have known, that bowel perforation was a possibility following an ablation, particularly as unusual procedure as described by Dr. Bannister's note.

39. On belief Nurse Hickman did not advise Dr. Bannister of the patient's complaints, and there is no documentation of Nurse Hickman having done so in the MOGA medical record.

40. An additional "Clinical Message" prepared by Nurse Hickman is part of the medical record dated September 6, 2013, after Casey Carter had died. The note provides:

> Pt c/o persistent nausea and vomiting. See message from pt on 9/5/13. c/o persistent cramping and bleeding. Reassured pt who has Phenergran on hand. F/U appointment 9/12/13. Advised to call back if sx persist.

41. Casey Carter used the Dulcolax suppository as prescribed on September 5, 2013 by Nurse Hickman.

42. The failure to report Casey Carter's complaints, and the prescription of a laxative in a patient for whom a bowel perforation should have been considered, constitutes gross negligence.

43. To a reasonable medical probability, had Casey Carter been evaluated by appropriate medical personnel on September 5, the bowel perforation would have been discovered, and with appropriate medical care as set forth above Casey Carter would have survived.

44. On the morning of September 6, 2013 Casey Carter was taken by her husband to the emergency department of Methodist Hospital - Olive Branch. A plain x-ray revealed a pneumoperitoneum - free air within the abdominal cavity.

45. The information was reported by the emergency physician to Helena Shannon, M.D., a physician employee of MOGA by 10:15 a.m. Presumably Dr. Shannon was the on call MOGA physician for Methodist-Olive Branch. Dr. Shannon requested the emergency physician to

transfer Casey Carter to Methodist Hospital-Germantown.

46. Casey Carter was taken by ambulance to Methodist Hospital-Germantown as instructed by Dr. Shannon.

47. After arrival at Methodist Hospital-Germantown the emergency physician contacted Michael Counce, M.D., a physician employee of MOGA. Presumably Dr. Counce was the on call MOGA physician for Methodist-Germantown. Dr. Counce recommended calling Dr. Bannister.

48. Dr. Bannister was contacted by the emergency physician prior to 1:12 p.m.

49. Dr. Bannister advised the emergency physician "she wants a surgical consult prior to taking to surgery."

50. By 1:53, the emergency physician documented that Dr. Douglas Hammond [a general surgeon] recommends "calling OR to take patient, will discuss with Bannister."

51. Casey was not taken to the operating room until approximately 4:30 p.m.

52. Dr. Bannister performed an exploratory laparotomy, a surgical procedure which involves opening the abdominal wall for exploration.

53. Operative findings by Dr. Bannister included "anterior uterine perforations x 3 and small bowel ileum perforation x 1."

54. After Dr. Bannister had opened the abdomen Dr. Hammond scrubbed in. Dr. Hammond confirmed a perforation of the small bowel, and diffuse contamination of the abdominal cavity with bowel spillage.

55. Dr. Hammond resected the injured portion of the small bowel, and performed an end-to-end anastomosis [re-connection] of the small bowel, and the abdomen was irrigated.

56. However, while on the operating table Casey went into hypotensive cardiogenic shock as a result of overwhelming sepsis. Despite attempted recussitation, Casey Carter died at 5:53 p.m.

57. Autopsy finding confirmed the cause of death as septic shock as a result of a perforation of the small bowel.

58. Dr. Bannister breached the acceptable standard of professional practice as set forth above in misusing the NovaSure device in direct contradiction to the manufacturer's instructions and warnings, and in perforating the uterus three times and in failing to recognize the three 3 mm perforations.

59. Nurse Hickman violated the acceptable standard of professional practice in failing to report Casey Carter's complaints to Dr. Bannister and in prescribing a laxative to a patient for whom a bowel perforation should have been a diagnostic consideration.

60. MOGA is vicariously liable for the acts or omissions of its actual and/or apparent agents Bannister and Hickman, who were acting within the scope and course of their employment.

61. As a direct and proximate result of the negligence of MOGA's employees Casey Carter died.

62 Plaintiff seeks all damages recoverable under applicable Tennessee law for the pecuniary value of the life of Casey Carter, including but not limited to, the pain and suffering of Casey Carter, the loss of earnings and earning capacity of Casey Carter, the medical and funeral expenses of Casey Carter, the loss, love and society and companionship and consortium suffered by Kevin Carter for the loss of his wife, and the loss, love and society and companionship and consortium suffered by the minor children of Casey Carter for the loss of their mother. Plaintiff seeks such and further damages as may be proved at trial.

63. Subject to discovery Plaintiff alleges the Defendant's employees likely prepared medical reports only after having met and/or consulted with their attorneys, malpractice carrier and others; thus Defendants may have intentionally falsified, destroyed or concealed material evidence with the purpose of wrongfully avoiding liability in the action.

64. Plaintiff alleges the actions that the acts of Dr. Bannister in performing the ablation twice in direct contravention of the manufacturers instructions, and in failing to discover the three 3 mm perforations of the uterus and perforation of the bowel, were sufficiently reckless to

warrant the imposition of punitive damages. Dr. Bannister has had similar conduct in the past. *See Brenda Ivy and Keith Ivy v. Lea M. Bannister, M.D. and Memphis Obstetrics & Gynecological Association, P.C.*, United States District Court for the Western Division of Tennessee, Cause No. 2:12-cv-02339-JTF-tmp. In addition, Plaintiff alleges that Dr. Bannister likely acted with others to prepare reports which may be false and misleading.

65. Subject to discovery Plaintiff further alleges the actions of Nurse Hickman in failing to report the patient's complaints and in prescribing a laxative were sufficiently reckless to warrant the imposition of punitive damages. In addition, Plaintiff alleges that Nurse Hickman likely acted with others to prepare reports which may be false and misleading.

66. Prior to maintaining this action, Plaintiff has given Defendants written notice of a potential claim in accordance with Tennessee Code Annotated §29-26-121 within the applicable statute of limitations and statute of repose. The Affidavit of Plaintiff's counsel and proof of service is attached hereto, and incorporated herein.[3]

67. Prior to the institution of this action, the undersigned counsel has consulted with one (1) or more experts who have provided a signed written statement confirming that upon information and belief they are (a) competent under §29-26-115 to express an opinion or opinions in the case; and (b) believe, based on the information available from the medical records concerning the care and treatment of the Plaintiff for the incident or incidents at issue, that there is a good faith basis to maintain the action consistent with the requirements of §29-26-115. A Certificate of Consultation by Plaintiff's counsel in the form prescribed by the Tennessee

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[3] Pursuant to prior instructions of the Clerk of this Court the "wet" signatures of this affidavit and its attachments have been redacted. Un-redacted documents are being furnished to opposing counsel, and are available for filing with the Court should they be requested or needed.

Administrative Office of the Courts is attached hereto and incorporated herein by reference.

WHEREFORE, premises considered, Plaintiff demands compensatory damages of and from the Defendants in an amount determined by the jury, not less than $10,000,000, plus all court costs assessed by the clerk. Plaintiff further seeks punitive damages as determined by the jury, prejudgement interest, and the award of attorneys' fees and expenses. Plaintiff demands a jury trial on all issues so triable.

Respectfully submitted,

MERKEL & COCKE, P.A.

/s/ William B. Raiford III

William B. Raiford, III (TSB # 12764,
MS Bar # 8390)
P.O. Box 1388
30 Delta Avenue
Clarksdale, MS 38614
662-627-9641
wraiford@merkel-cocke.com
Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on April 25, 2014, I electronically filed the foregoing document with the Clerk of the Court using the ECF system and sending a copy of the same to counsel of record via ECF system, e-mail, facsimile or U.S. Mail.

Buckner Wellford, Esq.
Baker Donelson Bearman Caldwell & Berkowitz
6060 Poplar, Ste. 440
Memphis, TN 38119
Attorneys for Defendants Memphis Obstetrics and Gynecological Association, P.C.

Randal H. Sellers, Esq.
Davis Florie, LLP
100 Brokwood Place, 7th Floor
P.O. Box 598512
Birmingham, AL 35259

THIS, 25th day of April, 2014.

/s/ William B. Raiford, III
William B. Raiford, III (Tenn. Bar No. 12764)